REMARKS

Claims 1, 3, 7-29, 45, 47, and 51-73 are pending in this application. Claims 1, 3, 7-29, 45, 47, and 51-73 were rejected under 35 U.S.C. § 103. Claims 1, 8, 9, 14, 20, 22, and 23 have been currently amended. Claims 2, 4-7, 15-19, and 24-73 have been canceled. Therefore, claims 1, 3, 8-14, and 20-23 are now pending. Support for the amendments can be found in the specification at least on the following pages:

Page 25, lines 29-32;

Page 29, lines 11-24; and

Page 30, lines 8-11.

No new matter has been added by this amendment. In view of the amendments, the following remarks, and Applicant's previous arguments of July 25, 2003, which are incorporated herein by reference, the rejections under 35 U.S.C. § 103 have been overcome.

In particular, the Examiner relied on *In re Kerkhoven* to support the § 103 rejections, stating that "one of ordinary skill artisan would be charged to have the knowledge to formulate various convention dosage forms of the well-known substances such as estradiol and methyltestosterone." Applicant respectfully disagrees with the Examiner's reliance on and interpretation of the law as stated in *In re Kerkhoven*, 626 F.2d 846, 205 U.S.P.Q. 1069 (CCPA 1980).

As recently explained in *Ecolochem, Inc. v. Southern California Edison Co.*, 227 F.3d 1361, 1372, 56 U.S.P.Q.2d 1065, 1073 (Fed. Cir. 2000), "[o]bviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination." *See also In re Geiger*, 815 F.2d 686, 688, 2 U.S.P.Q.2d 1276, 1278 (CCPA 1987)(reversing the § 103 rejection at issue because prior art

references suggesting ingredients claimed in the applicant's invention, but not suggesting applicant's combination of elements, do not make claims *prima facie* obvious and merely suggest the obviousness of trying combinations of prior art suggestions, which is inadequate grounds for the rejection).

In the pending application, the Examiner has not pointed to any teaching, suggestion, or incentive in the prior art to combine methyltestosterone in an oral dosage unit with estradiol to produce the claimed invention. The Examiner also does not point to anything in the prior art that teaches the dosage ranges claimed. The Examiner merely cites *In re Kerkhoven* and states that using methyltestosterone and the steroid of the claimed invention together, because both are used to treat menopausal disorders, would be obvious.

However, "defining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness." *Ecolochem*, 227 F.3d at 1372, 56 U.S.P.Q.2d at 1073 (quoting *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 880, 45 U.S.P.Q.2d 1977, 1981 (Fed. Cir. 1998)(internal quotation marks omitted); *see also Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985)(stating that when prior art references require selective combination to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight obtained from the invention itself); *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988)("One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention."); *In re Gorman*, 933 F.2d 982, 987, 18 U.S.P.Q.2d 1885, 1887 (Fed. Cir. 1991)("It is impermissible [] simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps.").

Nowhere in the prior art cited by the Examiner is a teaching, suggestion, or incentive to administer methyltestosterone and estradiol in combination, in the dosage ranges claimed, to treat female menopausal disorders.

Nowhere in Place (U.S. Pat. No. 6,117,446) is there a teaching, suggestion, or incentive to combine methyltestosterone and estradiol as in the present invention. The Examiner has failed to point to any teaching, suggestion, or incentive in Place to so combine methyltestosterone and estradiol to treat female menopausal disorders.

Nowhere in Remington's Pharmaceutical Sciences (1990) is there a teaching, suggestion, or incentive to combine methyltestosterone and estradiol as in the present invention. The Examiner has failed to point to any teaching, suggestion, or incentive in Remington's to so combine methyltestosterone and estradiol to treat female menopausal disorders.

Nowhere in Merck Index (11^{th} ed.) is there a teaching, suggestion, or incentive to combine methyltestosterone and estradiol as in the present invention. The Examiner has failed to point to any teaching, suggestion, or incentive in Merck Index to so combine methyltestosterone and estradiol to treat female menopausal disorders.

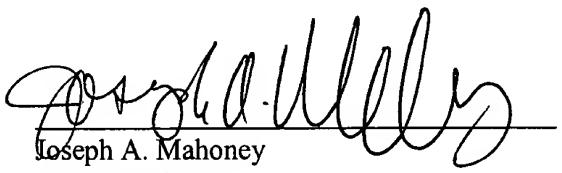
Nowhere in Leucuta et al. (Clujul Medical, 1983, 56: 371-76) is there a teaching, suggestion, or incentive to combine methyltestosterone and estradiol as in the present invention. The Examiner has failed to point to any teaching, suggestion, or incentive in Leucuta et al. to so combine methyltestosterone and estradiol to treat female menopausal disorders.

Nowhere in Rheology Modifiers Handbook (2000) is there a teaching, suggestion, or incentive to combine methyltestosterone and estradiol as in the present invention. The Examiner has failed to point to any teaching, suggestion, or incentive in Rheology Modifiers Handbook to so combine methyltestosterone and estradiol to treat female menopausal disorders.

Consequently, the Examiner has not established adequate grounds for the obviousness rejection under § 103. Therefore, Applicant respectfully requests reconsideration by the Examiner and withdrawal of the rejection.

With entry of the above Amendment and in view of the foregoing Remarks, Applicant respectfully submits that the application is in condition for allowance and respectfully requests that a timely Notice of Allowance or Advisory Action be issued in this application. None of Applicant's amendments are to be construed as dedicating any such subject matter to the public, and Applicant reserves all rights to pursue any such subject matter in this or a related patent application. If, in the opinion of the Examiner, a phone call may help to expedite prosecution of this application, the Examiner is invited to call Applicant's undersigned attorney at (312) 701-8979.

Respectfully submitted,



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